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October 23, 2015

VIA ECF AND FEDERAL EXPRESS

Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 5C
4th and Cooper Streets
Camden, NJ 08101

Re: **In re Benicar (Olmesartan) Products Liability Litigation**
MDL No. 2606

Dear Judge Schneider:

This will supplement our October 14, 2015 letter, address questions raised by Your Honor during the October 16 phone conference, and provide additional detail about document production status and the amount of time it will take to produce the documents currently requested by the Plaintiffs.

1. Estimate for Production.

Defendants have estimated that it will take sixteen months from today for the production of three categories of documents: (1) the 86 Daiichi U.S. and Forest custodians' documents (approximately 25 million documents collected); (2) the 54 Japan custodians' documents (approximately seven million documents collected); and (3) the non-custodial categories of documents described in this letter (approximately one million documents collected, excluding Defendants' applications, systems, and file shares).

These estimates are based on having 100 reviewers working full time on the U.S. documents and 50 reviewers working full time on the Japan documents. With this process in place, and based on over 30 million documents collected for these three categories, Defendants estimate that they would be now producing between 60-90 million pages of documents.

The sixteen-month estimate would be for the above three categories of documents only. We cannot provide an estimate for producing the documents from the 76 newly identified Daiichi U.S. and Forest custodians until those documents are collected and processed, and the volume is assessed. We also cannot provide at this time an estimate for producing the documents of any additional Daiichi Sankyo Company, Limited (DSC) custodians in Japan until the documents are collected and processed and the volume is

Andrew B. Joseph
Partner responsible for Florham Park Office

assessed. We anticipate the volume would be in the tens of millions of pages, perhaps even doubling the document count.

2. The Estimate is Consistent with or More Aggressive Than Other Recent Multi-District Litigations.

Document productions in multidistrict litigations require limits on discovery and then extensive time to focus on producing documents. The estimates for this MDL are consistent with or more aggressive than those in other MDL litigations. For example, in the ORTHO EVRA® Litigation (MDL 1742), 12 million pages were produced in a 33-month period. In the Yasmin/YAZ Litigation (MDL 2100), defendants produced approximately 3.3 million pages of documents per month for a period of over 30 months. In the ASR™ Hip Implant Litigation (MDL 2197) and Pinnacle Hip Implant Litigation (MDL 2244), 60 million pages were produced in 19 months, and the litigation is currently at 90 million pages in 53 months.

3. Why does this take so long?

Discovery takes so long because of the enormous quantity of documents that the plaintiffs have demanded to date.

As Mr. Slater said at the June 30 MDL hearing "litigations usually come down to a few needles in a massive haystack." *See* June 30, 2015 MDL Transcript, at 48. Mr. Slater has also referred to his search for the "silver bullet" (*See* June 30, 2015 MDL Transcript, at 48) and the "smoking gun" (*See* September 2, 2015 MDL Transcript, at 33). This is what he has called the "paranoia of a plaintiffs' lawyer." *See* September 24, 2015 MDL Transcript, at 78.

Federal Rule of Civil Procedure 26(b)(1) provides the standard for discovery, and it is not the "few needles" standard. The Court should continue to embrace this standard and measure the volume of and need for discovery by proportionality, not paranoia.

What's worse is that the Plaintiffs' demands here continue to evolve and grow.

Notwithstanding the clear and unmistakable statement by the Court that the custodian list for the U.S. companies was final, on October 19 after 5 p.m. Mr. Slater demanded to add another group of U.S. custodians and another 58 new Daiichi Japan custodians.

Defendants responded that the list of Daiichi U.S. custodians is final pursuant to CMO No. 13, and declined Plaintiffs' request.

The only way to compress the time for discovery is to shrink the "massive haystack." In our meet and confer on October 19, we asked Mr. Slater and Mr. Coffin to cut back on their requests. They refused.

We also asked Mr. Slater and Mr. Coffin to prepare a list of all discovery they wanted and to then prioritize it. They refused.

After multiple requests to prioritize the list of custodians, Plaintiffs finally on October 22 at 4:00 p.m. sent us a list of 27 names, which we are reviewing.

For some time the Defendants have asked Mr. Slater to prioritize what he wants, but he has refused to do so, in contrast to the plaintiffs' lawyers who started the litigation and within a few weeks gave the defense a list of "priority" documents, including the NDAs and INDs, which were then placed in line first for production.

What's left is for the Court to cut the plaintiffs' list if discovery is to be completed sooner. And, further, to limit the "drive by" discovery requests made in an unremitting stream by Mr. Slater.[i]

4. How have Plaintiffs' 606 search terms and 134 new custodians expanded the work?

Based on current information, the custodial files being collected for the 86 custodians identified by the plaintiffs contain approximately 300,000 documents per person, the majority of which are from e-mails. *See* August 28, 2015 Declaration of Eric Schwarz, Principal, Assurance Service, Fraud Investigations & Dispute Services at Ernst & Young, Dkt. 104-3. Adding the 76 additional Daiichi U.S. and Forest custodians requested by the Plaintiffs will potentially double this volume. Adding further the 58 additional custodians from Japan proposed by the plaintiffs Monday night (which more than doubles the original number) will further explode the volume.

After Mr. Slater demanded that search terms be re-negotiated last spring, Defendants proposed 89 search terms with 20 qualifiers on June 1, 2015. On August 28, 2015, the defense agreed to add an additional 80 search terms (not including variations) at the requests of the plaintiffs, for a total of 169 English and Japanese search terms, which includes a total of 606 variations. While the Defendants argued that the search terms should include qualifiers (*e.g.*, Benicar and sprue), instead of searching each term separately, plaintiffs rejected this and eventually, to move the process forward, Defendants agreed to stand alone search terms, understanding the number of documents would greatly increase and many would not be relevant or responsive.

Using the Defendants' original search terms with the connectors, the defense would have been required to review approximately two million documents. Agreeing to

use standalone terms, as demanded by Mr. Slater, increased that number to six million documents. Adding in the additional English search terms demanded by Mr. Slater increased the number of documents to be reviewed to eight million documents for the 86 custodians. This does not include the 76 new U.S. custodians demanded by Mr. Slater, nor does it include the 58 newly proposed additional Japanese custodians, nor does it include Japanese search terms, and it does not include approximately five million documents for the previously identified 54 Daiichi Japan custodians that need to be reviewed and produced.

Why do the search terms matter? First, there are a huge number of them. And second, most of the search terms Plaintiffs demand would be applicable to every product of Defendants and do nothing to help identify olmesartan documents from other materials (e.g. "abnorm*", "abdominal pain", or "DNA," or "GI" or "organ" or "warning"). This means that every single e-mail for the 86 custodians (and soon the 76 new custodians) that has the phrase "abdominal pain" or "DNA" or "warning" or "organ" must be retrieved, reviewed, and if relevant, processed. Additionally, at Plaintiffs' request, the names of the products themselves are being searched, so every document containing the terms Benicar, Azor, Tribenzor, *sartan, and olm* in it must to be reviewed.

Why does the number of custodians matter? First, there are likewise a huge number of them. Second, adding new custodians requires time and dedication of resources for collection and processing, adds hundreds of thousands of documents (and millions of pages) to the body of documents for review, slows the review process, and ultimately might not yield new documents because they are duplicative of the documents already collected. There is a point of negative returns when collecting documents from the people in the same departments at the same company who regularly copy one another on emails.

The above estimates are for custodial documents only. This is why Defendants have objected to the continued demands for "all" non-custodial documents, such as all adverse event reports and backup files, all foreign regulatory documents, all corporate transactional documents, and all the systems and applications within the company.

Non-custodial documents, such as departmental file shares, which have not been produced and which will yield the majority of non-custodial materials, and system productions, will require dedicated reviewers, e-discovery, and technology personnel to work full time on those documents.

5. What are the Steps Necessary to Collect, Review, and Produce Documents?

Large-scale document collections, reviews, and productions are time consuming, labor intensive, and expensive. There are three basic phases of work required to prepare

and produce documents: (a) collection and intake processing of source files identified for production; (b) review of the documents contained in those files; and (c) preparation of the production sets to be provided to opposing counsel. A detailed look at each of the steps explains why document production in this litigation particularly is so time consuming, labor intensive, and expensive.

Collection and Processing Phase.

The collection phase begins with interviews of numerous company personnel to identify which custodians have relevant personal files and to identify relevant non-custodial files, where they are located, and how to access them. This is a constant, iterative process. A majority of the documents to be produced in this matter are the custodial files of employees, and with the additional custodians demanded by Mr. Slater there are now different 216 custodians who worked on a product that has been on the market almost 15 years.

Collecting a custodian's documents involves several potential sources of data: the employee's email file, including any archives, documents in the employee's files on the server network, documents on the employee's company-issued computer, and hard copy files (paper or electronic media). Identifying and duplicating these materials is very time consuming. Arrangements must be made to copy the employee's computer while it is not in use. Paper files must be physically collected then sent to a vendor to be imaged into an electronic form, like a pdf. Foreign custodians require additional steps to comply with data privacy laws. The four olmesartan products were launched starting in 2002, they remain on the market, and company employees create new documents every day.

Data and documents are then processed and loaded into the Relativity database to be reviewed by a team of 100 attorneys. This involves staging and inventorying the materials, identifying and opening all zip files and similar document files, identifying and resolving any technical issues with the documents, generating hash values, and numerous other tasks, including quality control.

The next step is applying search terms to identify the documents that potentially relate to the four olmesartan products and the issues in this litigation from the millions of other documents relating to numerous other irrelevant topics that are also contained in the custodial files. Processing the search terms can take hours if not days, depending on the number of terms. With the new terms demanded by Mr. Slater, there are now 169 English and Japanese search terms, which includes a total of 606 variations to be applied to the documents of the 216 custodians.

According to our technology consultants, the average time to prepare, process, search and load 100,000 documents for review is three to four days. This case will involve millions of documents requiring such processing.

Review Phase

Document review is done by a large staff of full-time attorneys and other review personnel. A reviewer must review a document in its entirety to decide on relevance, protected status, and whether redaction of certain information is required. Every page of every document must be evaluated for content that must be redacted, such as patient or reporter identities in adverse event reports and related documents, patient identities in clinical study documents, sensitive data like passwords or social security numbers, certain highly protected personal information that must be redacted under foreign data privacy laws, and other items that the parties have agreed will be redacted pursuant to the ESI Protocol.

If redactions are required, a tiff image of the document must be generated and then the reviewer must create the redactions manually on the tiff image. Similarly the whole document must also be reviewed for relevancy. Many of the documents in every custodian file are inevitably determined to be irrelevant after review. This is, in part, because the search term list is designed to be broad enough to identify the relevant olmesartan-product documents. But by being broad, the search term list also picks up some non-relevant documents. More frequently, a document "family" has both irrelevant and non-relevant documents. An example is an email with two attachments, one attachment relating to Benicar and one relating to one of many different products marketed by these multiple pharmaceutical companies.

Reviews are simultaneously done for relevancy and privilege. The Court has appropriately rejected Mr. Slater's demand that the right and obligation for relevancy review be eliminated. On October 19, defendants proposed to Mr. Slater that privilege review could be eliminated or deferred by removing every document with a to/from/cc to an attorney from the pool of documents under consideration for production. Mr. Slater rejected this offer.

Production Phase.

After all of this, documents ready to be produced are processed, converted to tiff or prepared for production in native format, quality controlled, and then loaded on a hard drive. This process takes another two to three days before the documents can be sent to the Plaintiffs along with a letter identifying the applicable discovery responses and a production index.

6. What is Next

Plaintiffs' counsel have posed numerous questions about who does what when in the above process. This torrent of questions about the details of collections and review

processes are not productive, and the minute details of those processes are not material to the production schedule. Such detailed questioning is simply discovery about discovery. There is no magic fix or solution to increase the pace of production when the volume of documents that Plaintiffs demand is so enormous.

There is also no evidence before the Court that the defendants' processes and timeline for production are below or deviate from accepted standards. Indeed, they are consistent with or more aggressive than other MDLs. Injection of Mr. Slater further into the process and permitting micromanagement will not accelerate, it will delay.

Absent further requests, as we told Mr. Slater on October 19, the next six to nine months the focus of document collection and production will be on the following:

(a) *Custodial Productions*

- Bi-weekly productions of 1.5 to 2.5 million pages of Daiichi US custodial electronic and paper documents (original 55 custodians) – scheduled through Fall 2016

- Bi-weekly productions of 400,000-500,000 pages of DSC custodial electronic and paper documents (original 54 custodians) – scheduled through Fall 2016

- Bi-weekly productions of 200,000-300,000 pages of Forest custodial electronic and paper documents (original 31 custodians) – scheduled through Spring 2016

- Custodial electronic and paper documents for 76 additional custodians – documents are scheduled for collection and processing, with production schedule to follow

(b) *Documents from Japan (DSC)*

These categories of DSC documents, which were part of the August 26 hearing before Judge Johnson, have been identified by Mr. Slater in New Jersey as "priority" documents.

- DSC olmesartan development files – rolling production to start by November 2

- DSC olmesartan complaint files – rolling production to start by November 2

- DSC documents relating to the retention of persons to study the safety of olmesartan in Japan – rolling production to start by November 15

- DSC regulatory submissions - to be produced within the next 120 days or sooner

(c) *Court-Ordered Productions*

- 9,552 additional adverse event reports (pursuant to October 2, 2015 Order) – to be produced by November 2

- DOJ subpoenas and the enclosure letters reports (pursuant to October 2, 2015 Order) – to be produced by November 2

- Foreign regulatory documents for the United Kingdom, Spain, France, Germany, Canada, and Australia located in the US and Japan (pursuant to October 2, 2015 Order) – these documents being produced to the extent they are in custodial files, and other sources are being identified and will be produced within the next 60 days.

7. Conclusion

Defendants have produced over 6 million pages of documents so far, and that number continues to increase by two to four million pages of documents per month. So far, Defendants have spent $8.2 million in collection, review, processing, production, and technology consulting costs.

Defendants have provided substantial information to Plaintiffs to try to assist them in understanding the enormous volume of material and amount of work that will be necessary to produce the scope of document production that they seek in this litigation.

Plaintiffs continue to demand a massive production in an extremely short and unprecedented time frame, but give no realistic consideration to the amount of work and time necessary to accomplish the production. Defendants, on the other hand, are approaching the issue from a perspective that takes into account the work that will actually be required, and for that reason these estimates are reasonable and in line (if not more aggressive) than other MDLs.

The reality of MDL cases is that sixteen months for document production is the norm, not the exception. Typically trials commence two to three years after the start of the MDL:

- Xarelto – MDL created 12/12/14 – first trial set for 2/2017 – 26 months.

- Zoloft MDL – 32 months

- ASR MDL – 33 months
- Mirena MDL – 35 months
- Pinnacle Hip MDL – 40 months

It would be premature to set a deadline for document production until we have estimates for production of the documents of the 76 new U.S. custodians and 58 (or hopefully fewer) Japanese custodians. Thereafter, once a deadline is set, it should recognize the massive amount of work at hand and be consistent with those in other MDL proceedings. Short of that, the plaintiffs need to cut back on requests, custodians and search terms.

We appreciate the Court's attention to this matter.

Respectfully submitted,

DRINKER BIDDLE & REATH LLP

s/ Susan M. Sharko

cc: All Counsel of Record (via ECF)

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[i] For example, the Clinical Safety and Pharmacovigilance policies, guidance documents and ARGUS manuals/user guides flowing from Mr. Slater's meet and confer request required deployment of document personnel from review and collection of the custodial files to this task of questionable value and will result in over one thousand pages of documents including but not limited to the following:

1. Argus Safety Data Entry Convention (April 1, 2015) – internal Daiichi protocol regarding using the Argus system and data entry
2. Argus validation summary report and release memo – internal Daiichi document outlining its validation of the Argus system output
3. Argus user guide (published by Oracle, the vendor for Argus) – third party system instruction manual
4. FDA's Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (2001 draft guidance)

5. Serious Adverse Event Report (SAVER) Form Completion Guidelines.
6. Daiichi Sankyo Serious Adverse Event Narrative Template Instructions.
7. Adverse Event Reporting for Marketed Products.
8. SOP 602 Processing of IND Safety Reports. Version 4.0.
9. SOP 604 Processing of IND Protocol Amendment – Investigators.
10. SOP 517 Safety Signal Detection form Spontaneous Adverse Events Reports.
11. SOP 514 Developing the Serious Adverse Event Flow Plan.
12. SOP 501 Receipt Assessment Reporting SAE and EIU Data from Clinical Trials, Version 4.0.
13. SOP 501 Receipt Assessment Reporting SAE and EIU Data from Clinical Trials, Version 2.0.
14. SOP 501 Receipt Assessment Reporting SAE and EIU Data from Clinical Trials, Version 5.0.
15. SOP 502 Review Assessment and Reporting of AE and Non Study Sources.
16. SOP 514 Developing the Serious Adverse Event Flow Plan.
17. SOP 503 Examining Safety Date for Marketed Products.
18. SOP 517 Safety Signal Detection from Spontaneous Adverse Events Reports.
19. SOP 506 Internal Quality Review Process for Adverse Event Reports.
20. SOP 506 Internal Quality Control Process for Adverse Event Reports.
21. SOP 501 Receipt Assessment Reporting SAE and EIU Data from Clinical Trials, Version 3.0.
22. Serious Adverse Event [SA} Flow Plan. Version 4.0.
23. Serious Adverse Event [SA} Flow Plan. Version 3.0.
24. Serious Adverse Event [SA} Flow Plan. Version 2.0.
25. Communication Procedure for Safety-Related Regulatory Actions and Safety Information from Research/Investigational Reports.
26. Receipt, Assessment, and Reporting of Adverse Events from Study Sources. Version 6.0.
27. Receipt, Assessment, and Reporting of Adverse Events from Study Sources. Version 5.0.
28. Safety Signal Detection for Marketed Products. Version 2.0.

29. Safety Signal Detection for Investigational Products. Version 5.0.
30. Global Quality Control of MedDRA Term Selection. Version 1.0.
31. Receipt, Assessment and Reporting of serious Adverse Events from Investigational Studies. Version 5.0.
32. Signal Detection for Marketed and Investigational Products. Version 2.0.
33. MedDRA Coding Guideline. Version 1.0.
34. CSPV-SOI-015 Clinical Case Processing. Version 2.0.
35. RM-SOI-016 Spontaneous Case Processing. Version 2.0.
36. CSPV-SOI-015 Clinical Case Processing. Version 10.0.
37. CSPV-SOI-006 Generation of NDA Periodic Adverse Drug Experience Reports. Version 1.0.
38. CSPV-SOI-015 Clinical Case Processing. Version 4.0.
39. CSPV-SOI-020 Processing of Social Media Adverse Events. Version 2.0.
40. CSPV-SOI-005 Full Case Quality Review. Version 5.0.
41. RM-SOI-004 Individual Adverse Event Case File Order. Version 1.0.
42. CSPV-SOI-008 Generation and Distribution of Safety Notification Letters. Version 1.0.
43. CSPV- SOI 007 Quality Control Batch Review. Version 1.0.
44. CSPV-SOI-016 Spontaneous Case Processing. Version 4.0
45. CSPV-SOI-015 Clinical Case Processing. Version 9.0.
46. CSPV-SOI-006 Generation of NDA Periodic Adverse Drug Experience Reports. Version 2.0.
47. RM-SOI-007 Quality Control Batch Review. Version 1.0.
48. CSPV-SOI-007 Batch Quality Review. Version 4.0.
49. CSPV-SOI-015 Clinical Case Processing. Version 5.0.
50. CSPV-SOI-015 Clinical Case Processing. Version 2.0.
51. CSPV-SOI-015 Clinical Case Processing. Version 3.0.
52. CSPV-SOI-005 Peer Review of Expedited Cases. Version 1.0.
53. CSPV-SOI-016 Spontaneous Case Processing. Version 1.0.
54. CSPV-SOI-004 Individual Case File Order. Version 1.0.

55. CSPV-SOI-015 Clinical Case Processing. Version 8.0.
56. CSPV-SOI-014 Updating and Completing a Triage Sheet for SAE Reports. Version 1.0.
57. DSD RM-SOI-001.6 Handling of Serious Adverse Event Reports from Clinical Studies.
58. CSPV-SOI-011 Expedited Reporting of Serious Adverse Events from Clinical Studies. Version 9.0.
59. CSPV-SOI--011 Expedited Reporting of Serious Adverse Events from Clinical Studies. Version 1.0.
60. RM-SOI-004.0 Updating and Completing a Triage Sheet for SAE Reports.

Additionally, the Trial Master File for the 2010 ROADMAP study, which the Defendants offered to produce on August 26, 2015, appears to consist of over 1.5 million pages, and requires document personnel to travel to Germany to photocopy approximately 540 boxes of paper documents.